


Point-of-Care Testing: Home Is Where the Lab Is

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Introduction

In-center point-of-care (POC) testing is frequently utilized across multiple specialties. POC testing at home isn't entirely new either, and examples of well-established technologies include blood glucose monitoring or home monitoring for anticoagulation (1). Within nephrology, POC testing at home has largely been a niche technology until the coronavirus disease 2019 pandemic required that outpatient services be delivered virtually and away from traditional health care settings. This development has made nephrologists reconsider whether POC technology could also be used in the patient's home. Here, we provide a primer on POC at home for nephrologists. We describe examples of what is already available or in development, discuss unmet needs, and suggest avenues of future research.

What Is Already Available?

The technologies used for POC testing at home and criteria for evaluating any POC technology are reviewed in detail elsewhere (1), and a full discussion is beyond the scope of this article. In brief, such technology should be affordable, have a good balance between sensitivity and specificity, and be user-friendly, robust, and deliverable (1).

Urinalysis at Home via Smartphone Technology

Nephrology relies heavily on urinalysis, and it is therefore not surprising that digital urinalysis *via* smartphone technology is already widely used in a variety of clinical scenarios such as detection of urinary tract infection in renal transplant recipients (2); screening for albuminuria in pregnant, hypertensive, and diabetic patients; and monitoring glomerular disease (3). Measurement of both proteinuria- and albumin-creatinine ratios is available, with validation studies demonstrating excellent correlation to traditional methods (3). The frequency of home testing can be decided on an individual basis, depending on clinical need, as recently illustrated (3). It is legitimate to ask why one could not simply provide patients with traditional urine dipsticks for this purpose. However, the traditional approach has pitfalls such as intra- or interuser variability, uncertainty interpreting results, or technical difficulties such as color blindness. The

technology is easy to use, and the majority of patients preferred the smartphone-enabled approach (3).

POC Microsampling at Home for Monitoring of Creatinine and Tacrolimus

A significant percentage of workload for transplant teams, or for those caring for patients with glomerulonephritis, is around monitoring kidney function and levels of immunosuppressant drugs such as tacrolimus. Regular blood tests for this purpose have been a particular challenge during the pandemic and are also perceived as disruptive to school, work, or family life (4). This is particularly relevant for assessing adherence to immunosuppressive medication where the current standard of care only captures adherence before planned visits, and erroneous timing of traditional phlebotomy can lead to nontrough results. Microsampling techniques such as the Mitra device (Neoteryx/Spartan Biosciences, Nepean, Canada), which enable patients to do a finger-prick capillary blood test at home, are now well developed and are beginning to enter routine clinical practice. In brief, the blood sample is aspirated using capillary action onto a microsampling tip that absorbs a fixed amount of blood and can be posted to the laboratory (5). Analysis of the finger-prick sample is enabled by liquid chromatography tandem mass spectrometry, and correlation between whole blood venous samples and finger-prick blood samples is good. The coefficient of variation is 9% and 2%, and mean bias with venous blood is −5.6% and −6.5% for tacrolimus and creatinine, respectively (5). Long-term experience with this technology as a routine service for tacrolimus and ciclosporin in cardiothoracic transplantation is already available, with approximately 20% of immunosuppressant drug samples being collected at home (6). Cortisol and other hormones are also amenable to this approach, and further POC parameters, *e.g.*, hemoglobin A1c, C peptide, or severe acute respiratory syndrome coronavirus 2 antibodies, are in development.

What Is Currently in Development?

Analysis of Peritoneal Dialysis Fluid and Saliva

New POC technology has been used for the diagnosis of peritonitis in peritoneal dialysis patients (7). Although not yet trialed at home, if successful, it

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could aid in the triage of which patients require hospital attendance, and it could avoid unnecessary travel and anxiety for those who do not. In remote locations, clinicians could diagnose peritoneal dialysis peritonitis and prescribe treatment.

Another interesting new approach is saliva POC testing: urea dipstick testing has been used for the detection of advanced kidney failure in rural Malawi (8). Although predominantly focused on use in low-resource environments where creatinine measurements are not available, there may be a clinical utility elsewhere when finger-prick samples are problematic. It is also conceivable that other parameters are amenable to saliva.

Handheld Analyzers and the Smartphone as a Laboratory

POC testing *via* capillary finger-prick microsampling is already widely used by nephrologists in a range of settings such as inpatient care, acute clinics, and others, and a large variety of devices are commercially available. Typically, this approach is used to measure electrolytes, urea, creatinine, glucose, hemoglobin, hematocrit, and bicarbonate. Sampling issues in terms of volume sensitivity and hemolysis but particularly cost prevents these devices being widely used in patients' homes. Simpson and co-workers described the use of POC testing with a handheld analyzer device in nursing homes for patients with sepsis to help clinical decision making (9). It is tempting to think of a portable mini laboratory attached to the patient's smartphone. Such technology is not yet commercially available, although huge advances have already been made in microfluidic technology as a key enabler (10), and approaches with a mini laboratory linked to a smartphone for measuring other parameters already exist. The OmniVeritaM is currently being evaluated for the measurement of cell-free

DNA at home for lung cancer aftercare, but other uses and devices are certainly conceivable.

What Are Key Unmet Needs and Potential Pitfalls? Additional Parameters

Measurement of serum electrolytes is highly desirable in nephrology but not routinely feasible with for example microsampling techniques (Mitra). Liver function tests are also at least in part problematic due to the fact that some liver enzymes are also found in red blood cells and therefore affected by hemolysis, which only a whole blood assay could overcome. An equally difficult technical challenge exists for full blood count—another highly desirable parameter in an outpatient population. We predict that the next decade will see a variety of new technologies that will eventually allow for most or all of these parameters to be assessed through POC home testing. Another significant unmet need is testing markers of infection and inflammation at home to help clinical decision making (11). POC testing in nursing homes for both C-reactive protein and procalcitonin have been described already (12), and it is likely that microsampling technology will follow.

The Digital Divide, Integration into the Electronic Health Record, and Other Pitfalls

One key concern is the digital divide between parts of our patient population who have access to, and the confidence to use, technology and those who do not. We should ensure that we accommodate less IT literate patients in our clinical pathways and consider what support is required to overcome barriers. The same is true for patients with disabilities and those with language barriers.

Table 1. Limitations and pitfalls of point-of-care testing at home

| Problem | Suggestions to Mitigate Against |
|---|--|
| Digital divide | Ensure clinical pathways also work without POC at home technology; explore options to educate patients, relatives, and caregivers in the use of information technology |
| Language barriers | Work with commercial providers to ensure user interface, instructions, <i>etc.</i> has multiple language options |
| Patients with visual impairment and other disabilities | Seek views from patients with visual impairment; work with charities to see which POC at home technologies work for them |
| Patients could manipulate test results (<i>e.g.</i> , by providing a sample from somebody else) | Careful patient selection |
| Inappropriate too-frequent testing | Careful patient education and agreeing frequency of testing before use through shared decision making |
| Day-to-day biologic variation (potentially leading to increased patient anxiety and clinician workload) | Careful patient education before use, including expected variability |
| Speed of Internet connection (<i>e.g.</i> , in rural areas) | Work with commercial providers to ensure technology is robust under these circumstances |
| Connectivity to electronic health record | Consider early on and include pricing in business cases for POC testing at home |
| Reliance on equipment such as mobile phone | Consider approaches that are compatible with whatever equipment the patient already owns |
| Data protection and confidentiality | Take written consent; work with commercial providers to incorporate electronic options for consent into the technology |
| POC, point-of-care. | |

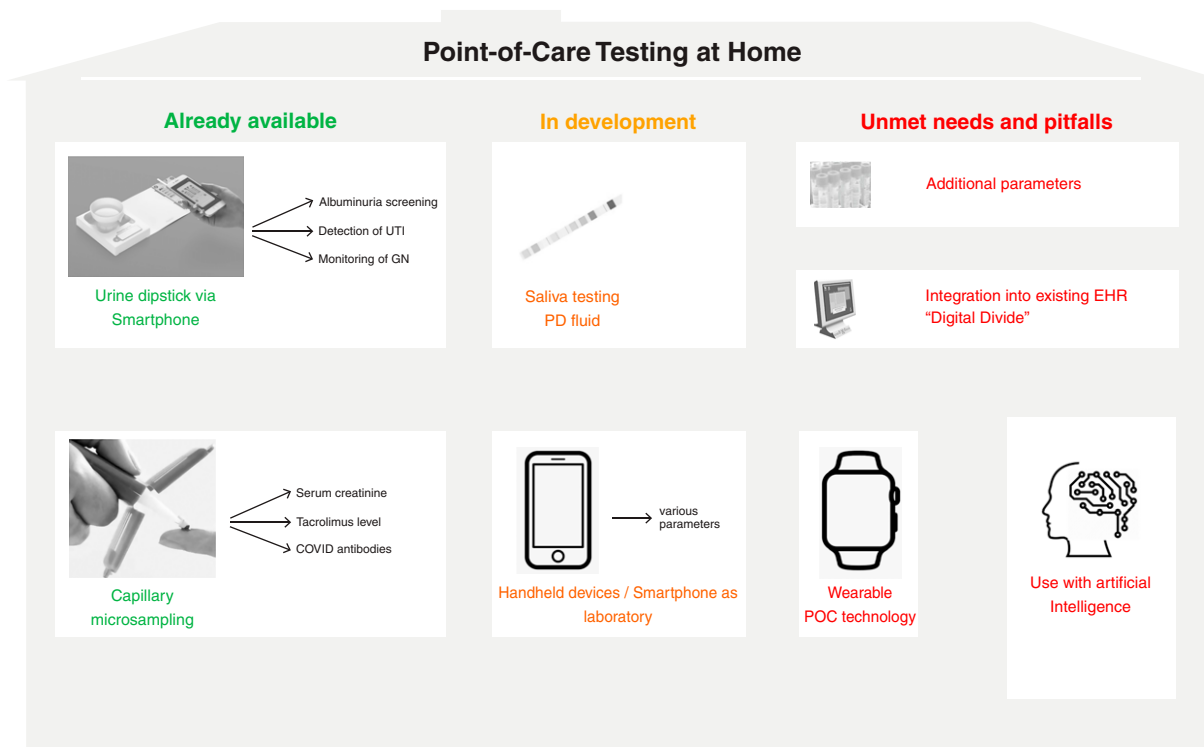


Figure 1. | POC testing at home. UTI, urinary tract infection; GN, glomerulonephritis; POC, point-of-care.

Day-to-day biologic variation in results is inevitable, and too frequent home testing has the potential to increase patient anxiety and workload for clinicians should minor fluctuations occur. Prior patient education is therefore fundamental, with careful explanations of expected variation and appropriate frequency of testing.

Technical issues also exist such as information governance and connectivity, *i.e.*, the need for all POC testing to integrate into existing electronic health record systems (13). We recently encountered this issue ourselves (3) and predict this will become even more relevant when clinicians use multiple platforms for POC testing at home concurrently. Enlisting patients and retrieving results is cumbersome under those circumstances, and institutions should include an interface to their electronic health record (and the associated cost) early on when implementing new technologies. Table 1 lists other potential pitfalls with POC testing at home.

Wearables and Artificial Intelligence

Looking further into the future and taking the concept of the smartphone as a laboratory one step further, the use of wearables may be considered an unmet need regarding POC testing at home. Calcium and pH can already be analyzed *via* wearable technology (14), and further applications are likely to emerge in the mid-term future. Finally, use of artificial intelligence seems a very attractive technology to combine with POC testing at home and to devise new clinical pathways that are safe but perhaps less intrusive and more cost-effective than current approaches.

Conclusion

Once regarded as niche technology, POC testing is beginning to arrive in patients' homes. This technology is increasingly attractive to nephrologists and integrates well into virtual reviews within a changed landscape of outpatient service provision (15). Cost efficiency, patient convenience, and concerns around climate change have acted as drivers of this development as part of increased virtual care provision overall. Some key laboratory parameters that we rely on for decision making are already available *via* POC home testing, and the list will certainly grow in the near future. We predict that within the next decade, POC at home testing (Figure 1) will become a routine part of remote care provision in developed countries. Nephrologists should now engage with the technology, consider how to integrate it into their models of care, and work with the industry on unmet needs.

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Author Contributions

A. Woywodt was responsible for conceptualization; and all authors wrote the original draft of the manuscript and reviewed and edited the manuscript.

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